

Notice of Allowability	Application No.	Applicant(s)	
	09/543,407	WHITE ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2 June 2004.
2. ☒ The allowed claim(s) is/are 56-59, 65-68 and 74, renumbered 1-9, respectively.
3. ☒ The drawings filed on 02 June 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>8/19/2004</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

L. R. F. Smith
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Art Unit: 1645

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Qing Lin on August 19, 2004.

2. This Office Action is responsive to Applicant's response June 2, 2004. All rejections of record are withdrawn in view of Applicant's remarks. Claims 56-59, 65-68 and 75 are allowed and renumbered 1-9, respectively.

3. The application has been amended as follows:

In the specification:

Page 36, replace the second paragraph starting with line 1 with:

Secondary structural analysis of AgfA. Secondary structure analysis of AgfA was determined using several programs including: Alexis version 1.2 SEQSEE 10 (*Wishart et al.*, 1994), PPSP (Parker & Hodges, 1991a; Parker & Hodges, 1991b), Sequences Annotated by Structure (~~www.biochem.ucl.ac.uk/cgi-bin/sas~~) (biochem.ucl.ac.uk/cgi-bin/sas), Gibrat Secondary Structure Prediction and Hierarchical Neural Network (pbil.ibcp.fr/NPSA, NNPredict, (~~www.cmcpharm.ucsf.edu/cgi-bin/nnpredict.pl~~) (cmcmpharm.ucsf.edu/cgi-bin/nnpredict.pl), PhDsec (www.embl-heidelberg.de/predictprotein) (embl-heidelberg.de/predictprotein) and Predator (www.embl-heidelberg.de/predator) (embl-heidelberg.de/predator).

4. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests a recombinant nucleic acid molecule that encodes a chimeric AgfA fimbrin polypeptide comprising at least one heterologous antigen, wherein said nucleic acid molecule encodes a chimeric polypeptide selected from the group consisting of SEQ ID NO: 12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, and SEQ ID NO:30. The prior does not teach or suggests a host cell comprising a recombinant nucleic acid molecule recombinant nucleic acid molecule that encodes a chimeric AgfA fimbrin polypeptide comprising at least one heterologous antigen,

Art Unit: 1645

wherein said nucleic acid molecule encodes a chimeric polypeptide selected from the group consisting of SEQ ID NO: 12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, and SEQ ID NO:30.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1645

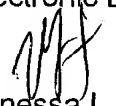
Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
August 19, 2004

CLEAN COPY OF CLAIMS

56. A recombinant nucleic acid molecule that encodes a chimeric AgfA fimbrin polypeptide comprising at least one heterologous antigen, wherein said nucleic acid molecule encodes a chimeric polypeptide selected from the group consisting of SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, and SEQ ID NO:30.

57. The recombinant nucleic acid molecule according to claim 56 wherein said recombinant nucleic acid molecule is present in an expression vector, said expression vector producing the chimeric polypeptide when expressed in a host cell.

58. A host cell comprising the recombinant nucleic acid molecule according to claim 57 wherein said host cell produces the chimeric polypeptide.

59. The host cell according to claim 58 wherein said host cell produces stable fimbriae comprising the chimeric polypeptide.

65. The host cell according to claim 58 or claim 59 wherein said host cell is selected from the group consisting of a strain of *Enterobacteriaceae*, *Escherichia coli*, and *Salmonella*.

66. The recombinant nucleic acid molecule according to claim 56 wherein said recombinant nucleic acid molecule is in the chromosome of a host cell.

67. The recombinant nucleic acid molecule according to claim 66 wherein said host cell produces the chimeric polypeptide.

68. The recombinant nucleic acid molecule according to claim 66 wherein said host cell produces stable fimbriae comprising the chimeric polypeptide.

74. The recombinant nucleic acid molecule according to any one of claims 66-68 wherein said host cell is selected from the group consisting of a strain of *Enterobacteriaceae*, *Escherichia coli*, and *Salmonella*.